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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard Allen Brown

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EXAMINER

CAPPS, KEVIN J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/047,817	Applicant(s) BROWN, RICHARD ALLEN	
	Examiner Kevin J. Capps	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,11-32 and 53-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-9,11-32 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2005, has been entered.

Status of the Claims

2. Applicant's claim amendments filed on December 19, 2005, are acknowledged. Claims 1, 28, 29 and 58 were amended and claims 2-4, 6 and 52 were cancelled in the amendments filed on December 19, 2005. No new matter has been incorporated. Claims 1, 7-9, 11-32 and 53-58 are pending and examined on the merits herein.

3. Applicant's submissions of rebuttal arguments ("Remarks/Arguments") on December 19, 2005, and March 20, 2006, as well as the declaration ("Third Declaration Under 37 CFR § 1.132") are acknowledged. The arguments and declaration are addressed herein.

4. Claims 1, 7-9, 11-32 and 53-58 stand rejected under 35 USC § 103 over Hollenberg et al. (US 5,143,722) in view of Collin et al. (US 5,656,672) and Guthauser (US 5,162,378) and under 35 USC § 103 over Stepniewski et al. (US 5,599,533) in view

of Rappoport (US 5,730,991) and Dorogi et al. (US 5,882,661) as of the previous final rejection mailed on August 18, 2005.

5. In light of Applicant's arguments, the rejection under 35 USC § 103 over Hollenberg et al. (US 5,143,722) in view of Collin et al. (US 5,656,672) and Guthauser (US 5,162,378) is withdrawn.

6. The rejection of claims 1, 7-9, 11-32 and 53-58 under 35 USC § 103 over Stepniewski et al. (US 5,599,533) in view of Rappoport (US 5,730,991) and Dorogi et al. (US 5,882,661) is maintained and the arguments are addressed below.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1, 7-9, 11-32 and 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stepniewski et al. (US 5,599,533) in view of Rappoport (US 5,730,991), and further in view of Dorogi et al. (US 5,882,661).

10. Stepniewski et al. teach a stabilized water-in-oil emulsion comprising an organopolysiloxane elastomer (0.1 to 12% by weight), a vehicle (1 to 90% by weight), at least one stabilizing agent selected from the group consisting of electrolytes, a polyol, an alcohol, a hydrocolloid and mixtures thereof (0.01 to 20% by weight), at least one surfactant (0.01 to 20% by weight), and an aqueous component (claim 1; column 2, lines 20-35). Stepniewski et al. teach a make-up composition comprising said emulsion and at least one pigment (claim 31). Stepniewski et al. exemplify a cosmetic foundation comprising said emulsion (Example 2). Stepniewski et al. exemplify the same preferred elastomers as are preferred in the instantly claimed compositions (see column 2, lines 36-55 of Stepniewski et al. and p. 10, line 27-p. 11, line 12 of the instant specification). Stepniewski et al. teach that the vehicle preferably comprises a silicone oil (column 3, lines 1-20). Stepniewski et al. exemplify cyclomethicone, dimethicone, and mixtures thereof as preferred silicone oils (column 2, lines 66-67 and column 3, lines 1-20). Stepniewski et al. teach that preferred electrolyte stabilizing agents are "alkali metal salts and alkaline earth salts, especially the chloride, borate, citrate, and sulfate salts of sodium, potassium, calcium and magnesium" (column 3, lines 46-54). Stepniewski et al. teach that other preferred stabilizers include "organo-modified clays such as quaternium-18-hectorite." (column 4, lines 3-4). Stepniewski et al. teach that the hydrocolloid includes thickening agents (column 3, lines 55-57). Stepniewski et al. teach

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that cetyl dimethicone copolyol is a preferred surfactant (claim 40; column 4, lines 26-28; Example 1). Stepniewski et al. teach that the aqueous phase should constitute 10-60% by weight, and preferably 30-45% by weight, of the emulsion (column 4, lines 54-56). Stepniewski et al. teach that the composition can comprise other additives, including "glycols...sunscreen agents...preservatives, such as known parabens" (column 4, line 63-column 5, line 2). Stepniewski et al. teach that when the emulsion is used as a make-up, pigments are included (column 5, lines 2-3). Stepniewski et al. exemplify iron oxides and titanium dioxide as preferred pigments (claim 32; column 5, lines 3-7; Example 2).

11. Stepniewski et al. do not teach octyl methoxycinnamate as a preferred sunscreen agent. Stepniewski et al. do not teach the preferred herein claimed preservatives phenoxyethanol, methylparaben or propylparaben. Stepniewski et al. do not teach that the compositions comprising the emulsion are stable for at least three months at about 50 °C.

12. Rappoport teaches that octyl methoxycinnamate is a preferred sunscreen agent for use in topical compositions (column 17, lines 17-26).

13. Dorogi et al. teach that phenoxyethanol, methyl paraben and propyl paraben are preferred preservatives for use in topical compositions (column 5, lines 17-19).

14. It would have been obvious to a person of ordinary skill in the art to add octyl methoxycinnamate as a sunscreen agent and phenoxyethanol, methylparaben or propylparaben as a preservative to the compositions of Stepniewski et al. to arrive at the instantly claimed compositions.

15. The person of ordinary skill in the art would have been motivated to add octyl methoxycinnamate to the compositions of Stepniewski et al. because Rappoport teaches that octyl methoxycinnamate is a preferred sunscreen agent for use in topical compositions. The person of ordinary skill in the art would have been motivated to incorporate phenoxyethanol, methylparaben or propylparaben into the compositions of Stepniewski et al. as preservatives because Dorogi et al. teach that phenoxyethanol, methyl paraben and propyl paraben are preferred preservatives for use in topical compositions. The person of ordinary skill in the art would have expected success in incorporating the herein claimed sunscreen agents and preservatives because Stepniewski et al. disclose broadly the incorporation of sunscreen agents and preservatives, including known parabens, and Rappoport and Dorogi et al. teach that the herein claimed sunscreen agents and preservatives have been successfully used in topical compositions. Further, although Stepniewski et al. do not teach that the compositions are "stable for at least three months at about 50 °C," they do disclose that the compositions are stable in general. The recitation that the instantly claimed compositions are "stable for at least three months at about 50 °C" is an inherent feature of the product rendered obvious by the teachings of the prior art. It has been established that "[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention." (See MPEP § 2145, "II. Arguing Additional Advantages or Latent Properties"). It has also been established that "[g]ranting a patent on the discovery of an unknown but inherent function... 'would re-move from the public

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that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art.” See MPEP § 2145, “II. Arguing Additional Advantages or Latent Properties”).

16. Because all of the components of the herein-claimed topical compositions have been disclosed in the prior art for incorporation into topical compositions, the optimization of the amount of the components is not considered inventive because it is a matter of routine experimentation for the skilled artisan possessing the above-cited prior art. Applicant’s attention is directed to *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) which states, “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See MPEP § 2144.05, “II. Optimization of Ranges”.

17. Claims 1, 7-9, 11-32 and 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stepniewski et al., Rappoport, and Dorogi et al. as applied to claims 1, 7-9, 11-32 and 53-58 above, and further in view of Collin et al. (US 5,656,672).

18. Stepniewski et al. teach the water-in-oil emulsions comprising, among other things, sunscreen agents, preservatives, and 0.01-20% by weight of the preferred surfactant cetyl dimethicone copolyol, as outlined above.

19. As stated above, Rappoport teaches that octyl methoxycinnamate is a preferred sunscreen agent for use in topical compositions, and Dorogi et al. teach that phenoxyethanol, methyl paraben and propyl paraben are preferred preservatives for use in topical compositions.

20. Stepniewski et al., Rappoport, and Dorogi et al. do not teach incorporation of the surfactant cetyl dimethicone copolyol at the herein claimed range of 3-6% by weight.

21. Collin et al. teach water-in-oil compositions which preferably comprise "a silicone-containing emulsifying agent, which is used in a proportion of from 0.5% to 10%, and preferably from 1% to 6%, of the total weight of the emulsion." (column 3, lines 36-49). Cetyl dimethicone copolyol (also ABIL EM-90) is exemplified as a preferred emulsifying agent (claim 16; column 3, lines 36-49; Examples 2 and 4). Collin et al. exemplify two cosmetic compositions wherein the amount of cetyl dimethicone copolyol is 3% by weight of the composition (Examples 2 and 4).

22. It would have been obvious to a person of ordinary skill in the art at the time of invention to incorporate octyl methoxycinnamate as a sunscreen agent and phenoxyethanol, methylparaben or propylparaben as a preservative into the compositions of Stepniewski et al., and to add cetyl dimethicone copolyol at the herein-claimed ranges, to arrive at the instantly claimed compositions.

23. The person of ordinary skill in the art would have been motivated to incorporate octyl methoxycinnamate, phenoxyethanol, methylparaben, and propylparaben in the compositions of Stepniewski et al. and would have expected success for the reasons stated above. The person of ordinary skill in the art would have been motivated to incorporate cetyl dimethicone copolyol in the compositions of Stepniewski et al. at the herein claimed ranges because Collin et al. teach that 1 to 6% by weight is a preferred range for the surfactant in water-in-oil emulsions, and because Collin et al. exemplify the incorporation of cetyl dimethicone copolyol at 3% by weight in two different cosmetic

compositions. The person of ordinary skill in the art would have expected success because Stepniewski et al. teach that cetyl dimethicone copolyol can be incorporated at 0.01 to 20% by weight of stable water-in-oil emulsions, and Collin et al. teach that 1 to 6% by weight, and specifically 3% by weight, is a preferred range of cetyl dimethicone copolyol from within the range taught by Stepniewski et al. for use in water-in-oil-emulsion-based cosmetic compositions.

Response to Arguments

24. Applicant's rebuttal arguments filed on December 19, 2005, and March 20, 2006, regarding the rejection under 35 USC § 103 over Hollenberg et al. in view of Collin et al. and Guthauser have been fully considered and the rejection is accordingly withdrawn. The motivation to incorporate cetyl dimethicone copolyol into the composition of Hollenberg et al. as set forth in the previous Office Action is that Hollenberg et al. teach the optional inclusion of a surfactant with an HLB value of from 2 to 12, and Guthauser teaches that cetyl dimethicone copolyol has an HLB value of from 4 to 6. Applicant argues that because Hollenberg et al. teach that the optional surfactant with an HLB value of from 2 to 12 should be silicone-free, there would be insufficient motivation to combine cetyl dimethicone copolyol with the composition of Hollenberg et al. In light of this argument, the rejection under 35 USC § 103 over Hollenberg et al. in view of Collin et al. and Guthauser is withdrawn.

25. Applicant's rebuttal arguments filed on December 19, 2005, and March 20, 2006, regarding the rejection under 35 USC § 103 over Stepniewski et al. in view of

Rappoport and Dorogi et al. have been considered, but are not persuasive. Also, the declaration under 37 CFR 1.132 filed March 20, 2006, is insufficient to overcome the rejection of claims 1, 7-9, 11-32 and 53-58 based upon the rejection under 35 USC § 103 over Stepniewski et al. in view of Rappoport and Dorogi et al. as set forth in the last Office Action for the reasons set forth below.

26. Applicant states that "Rapaport and Dorogi et al. do not even mention the use of a cetyl dimethicone copolyol in any amount, let alone in the amount of about 3-6 wt%."

The references Rapaport and Dorogi et al. were provided as motivation to incorporate the herein-claimed sunscreen agent octyl methoxycinnamate and the herein-claimed preservatives phenoxyethanol, methylparaben or proylparaben into the compositions of Stepniewski et al. No other reference is needed to motivate the person of ordinary skill in the art to incorporate cetyl dimethicone copolyol into the compositions of Stepniewski et al. because Stepniewski et al. teach that cetyl dimethicone copolyol is a preferred surfactant for their compositions (claim 40; column 4, lines 26-28; Example 1).

27. In the rebuttal arguments filed on December 19, 2005, and March 20, 2006, Applicant avers that the instantly claimed compositions are not rendered obvious by the combined teachings of Stepniewski et al., Rappoport and Dorogi et al. because, whereas Stepniewski et al. teach incorporation of a surfactant at 0.01 to 20% by weight, and exemplify incorporation of 0.5% by weight of the preferred surfactant cetyl dimethicone copolyol, it was discovered by the present inventor that incorporation of cetyl dimethicone copolyol at 3-6% by weight of the composition provides "unusual stability" to the compositions.

28. Applicant points to the Declarations filed under 37 CFR § 1.132 on September 2, 2004, May 27, 2005, and March 20, 2006, as evidence of the “unusual stability” of the compositions. First, it is noted that it is Applicant's burden to demonstrate unexpected results over the prior art. (See MPEP 716.02, also 716.02 (a) - (g)). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be “clear and convincing” *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

29. Applicant avers that the Declaration filed on September 2, 2004, demonstrates that compositions comprising amounts of cetyl dimethicone copolyol within the range taught by Stepniewski et al. (1% and 8% by weight), but outside of the instantly claimed range 3-6% by weight), were “not similarly stable”. The results of the Declaration are not clear and convincing because it is unclear what the compositions that were tested actually comprise. Although Applicant states that the compositions were prepared according to Example 1 and that “[t]he only component to vary from Example 1 was the amount of cetyl dimethicone copolyol,” the actual identity of the compositions remains a mystery because it would be impossible to make a composition according to Example 1 wherein the only component that was altered was the amount cetyl dimethicone copolyol. This is because altering the amount of cetyl dimethicone copolyol in Example 1 to either 1% or 8% by weight would generate a composition with a total weight percent

of less than or more than 100%. Thus, because the identity of the compositions tested in the experiments are unknown, the results indicating increased stabilities observed for compositions comprising the herein-claimed range of cetyl dimethicone copolyol are not convincing.

30. Applicant avers that the Declarations filed on May 27, 2005, and March 20, 2006, demonstrate that compositions comprising the herein-claimed range of cetyl dimethicone copolyol, namely samples C-G, are unusually stable. The Declaration filed on May 27, 2005, suffers from the same problem stated above, namely, that it is unclear what comprises the compositions that are being tested. Samples C and D are said to be made according to Example 1 and that "[t]he only component to vary from Example 1 was the amount of cetyl dimethicone copolyol." For the reasons stated above, this is impossible. Therefore, the results cannot be considered clear and convincing because the identity of the compositions is unknown. The Declaration filed on March 20, 2006, demonstrates the stability of compositions comprising the herein-claimed range of cetyl dimethicone copolyol. In this Declaration, the identity of the Samples E-G is exemplified. It is noted by the Examiner that the stability observed for these compositions is expected because Stepniewski et al. teach that the emulsions formulated in the manner that they disclose are stable (See, for example, the claims).

31. Furthermore, because all of the Samples in the Declaration filed on March 20, 2006, comprise amounts of cetyl dimethicone copolyol within the herein-claimed range, no comparison between compositions comprising amounts of cetyl dimethicone copolyol within the range taught by Stepniewski et al. and but outside the herein-

claimed range demonstrating "unusual stability" can be made. Also, the results for Samples E-G cannot be compared to Samples A and B from the Declaration filed on September 2, 2004, because, again, it is unclear what Samples A and B actually comprise.

32. Therefore, because the results of the above-cited Declarations are either unclear or consistent with the results expected from the combined teachings of Stepniewski et al., Rappoport and Dorogi et al., the instantly claimed compositions are considered obvious in view of Stepniewski et al., Rappoport and Dorogi et al.

Conclusion

33. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin J. Capps whose telephone number is (571) 272-8646. The examiner can normally be reached on Monday-Friday, 7am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KC



**SAN-MING HUI
PRIMARY EXAMINER**